A Potential Pitfall in the Use of the Monorail System for Carotid Stenting

A Technical Case Report

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Summary

The use of EPDs seems to be necessary for safe CAS. Though the monorail system may offer advantages for a single operator, we caution its use with certain aortic arch anatomies.

In such anatomies, using an OTW system or at least a 300 cm filter wire or devices that support wire extension will remedy some complications, such as the loss of the guiding sheath. As in our case, the added advantage of a 300 cm filter wire enabled us to avoid a poor outcome or an emergency vascular surgery.

Introduction

Carotid angioplasty and stenting (CAS) has become part of the armamentarium for stroke prevention in high-risk patients with symptomatic cervical carotid artery atherosclerotic disease. Data from several multicenter studies have shown that CAS might be safer than, and as efficacious as, carotid endarterectomy (CEA). Therefore, CAS is anticipated to surpass CEA in the treatment of carotid atherosclerotic disease. Despite being a technically simple procedure, CAS can occasionally present unwanted surprises. This report describes a patient in whom an apparent straightforward case nearly turned into a disaster due to balloon retrieval failure. It illustrates a potential drawback of monorail systems and ways to deal with similar situations that may arise in surgical endovascular practice.

Case Report

A 57-year-old man with recurrent transient ischemic attack (TIA) was referred to the Neurointerventional Service for carotid stent placement. Antiplatelet therapy consisting of clopidogrel 75 mg/day and aspirin 325 mg/day was administrated for four days prior to the intervention. The endovascular procedure was performed under local anesthesia. The patient received an initial bolus of heparin followed by continuous infusion to keep the activated clotting time around 300 seconds. An initial four vessel angiogram with an aortogram was used to assess the cervico-cephalic circulation (figure 1). Cerebral angiography revealed a normal aortic arch and stenosis of the common carotid bifurcation bilaterally.

After selective catheterization of the left external carotid artery with a 5 F multipurpose catheter this was exchanged over a guidewire for a 6 F shuttle sheath (Cook, Bloomington, IN), which was placed into the distal left common carotid artery. The stenotic segment of the left internal carotid artery was then crossed with a FilterWire EX (Boston Scientific, Natick, MA), and the filter basket was opened in the distal cervical segment of the left internal carotid artery. A 9 x 40 mm Precise stent (Cordis, Miami, FL) was coaxially advanced over the 0.014" wire and deployed into the stenotic segment. Angioplasty was subsequently performed with a 6 x 20 mm Savvy balloon (Cor-

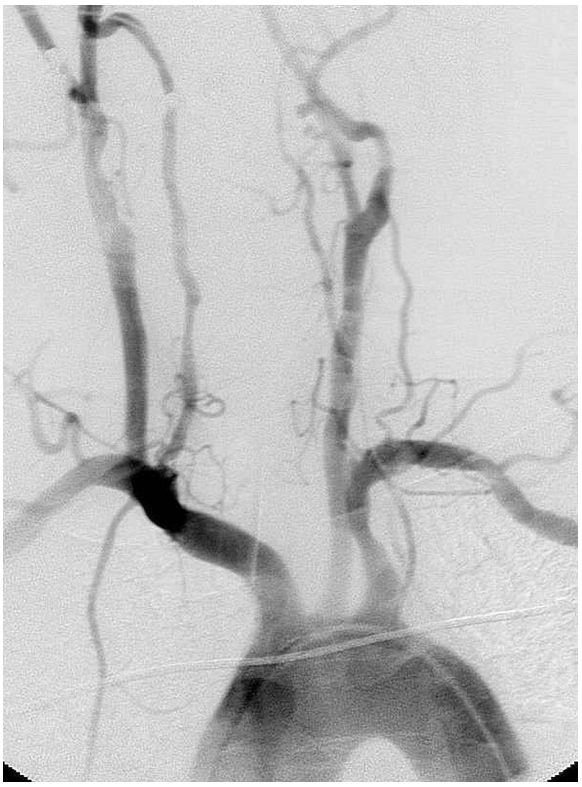

Figure 1 Aortogram demonstrating normal aortic arch anatomy. Diffuse atheromatous-type changes are seen involving the great vessels and branches.

dis, Miami, FL) according to manufacturer's recommendation. After deflation, the balloon could not be pulled below the distal end of the 6 F sheath despite several attempts. As in any of our neurointerventional procedures we exercise caution and use delicate manipulation of all endovascular tools. Therefore we considered it prudent to pull the guiding sheath into the internal iliac artery before using considerable force to retrieve the balloon. Having lost the appropriate support, we decided to withdraw the Shuttle sheath along with the balloon and exchange it for a short 6 F sheath over the 0.014" filter wire left in place. We then introduced the retrieval sheath provided with the protective system hoping to close the filter. The advancement of the monorail retrieval sheath over the 0.014'' wire without any guiding support caused the filter to descend so its nitinol loop moved inside the stent and it could not be pushed in or pulled out. Fluoroscopic examination revealed that the wire had prolapsed into the aortic arch and had curled on its own (figure 2). The wire was then straightened, and several more attempts to advance the retrieval sheath were unsuccessful due to inability of the sheath to negotiate the steep aorta-left common carotid angle and repeated curling of the wire at the arch level.

Next, we removed the retrieval sheath and advanced a soft 4 F multipurpose catheter over the 0.014'' wire kept under slight tension. This maneuver allowed us to push the malleable catheter into the left internal carotid artery and resheath the filter basket. Post stent/angioplasty angiogram demonstrated complete resolution of the stenotic segment (figure 3) and no evidence of embolic complications.

Gross examination of the balloon revealed that it had been distended and crinkled at the distal tip as if it had been pulled forcefully through the supporting sheath while partially inflated (figure 4). These redundant folds resulted in a kind of ball at the balloon's end preventing its passage down through the guiding sheath.

Discussion

Stroke is one of the leading causes of mortality and disability amongst the adult population. The incidence of new strokes in the United States is about 500,000 cases per year, with an estimated cost of $56.8 billion [1]. Carotid artery disease may be responsible for 12% of these cases [2]. The North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS), two large prospective randomized trials, have demonstrated the potential of CEA in reducing the risk of stroke in certain patients with extracranial carotid artery stenosis [3,4].

Alongside CEA, CAS has emerged as a safe and less invasive alternative. CAS, however, has generated much discussion due to the high potential for distal embolization. The use of embolic protection devices (EPDs) has greatly overcome these concerns [5,6]. The SAPPHIRE is a recently completed randomized prospective trial comparing CAS with CEA in high-risk patients who would have been excluded from the above surgical studies. This study has substantiated the use of EPDs to minimize stoke complications [7].

With the current approval of CAS by the Food and Drug Administration (FDA), an increasing number of centers are expected to of-

fer this technique for carotid occlusive disease with a proportional increase in the use of EPDs. Despite claimed advantages, the use of EPDs adds extra complexity to the procedure and may not be free of complications. Arterial dissection, severe vasospasm, detachment of the device from the guidewire, entrapment of the device inside the stent, and difficulty in passing the retrival catheter through the stented segment have been described [8,9]. In addition, the inherent issues related to the use of EPDs in tortuous anatomy and tight stenosis might prolong the procedural time and further increase the chance of complications. In a large series of 442 patients who underwent CAS with different types of EPDs, device-related complications were reported in 0.9% [9].

There are three different types of EPDs available for the treatment of occlusive carotid disease. The first form of protection started to be developed in the early nineties. It consists of a balloon temporarily placed in the internal carotid artery to occlude the blood flow distal to the culprit lesion prior to CAS. Following

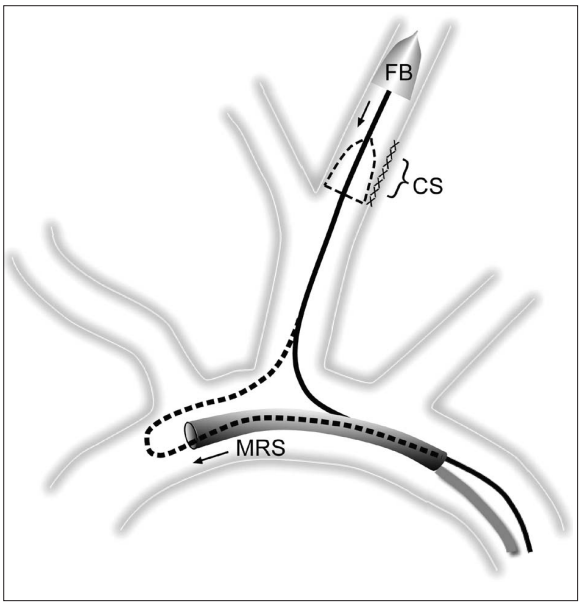

Figure 2 Schematic representation of the aortic arch. The advancement of the monorail retrieval sheath (MRS) caused both the filter basket (FB) to descend inside the carotid stent (CS) and the wire to curl at the arch level. These position changes are depicted by the dashed lines.

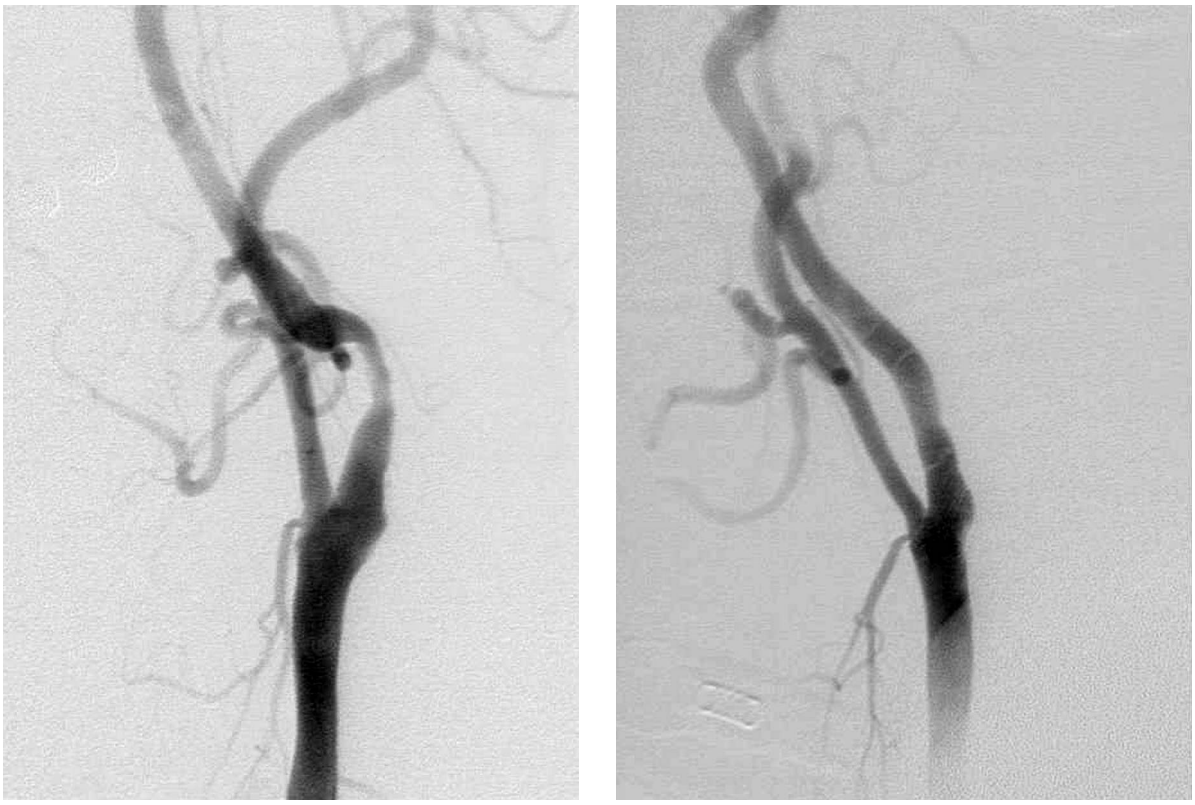

Figure 3 A) Digital angiography in lateral view of the left common carotid shows the target lesion. B) Post intervention imaging demonstrates resolution of the stenosis

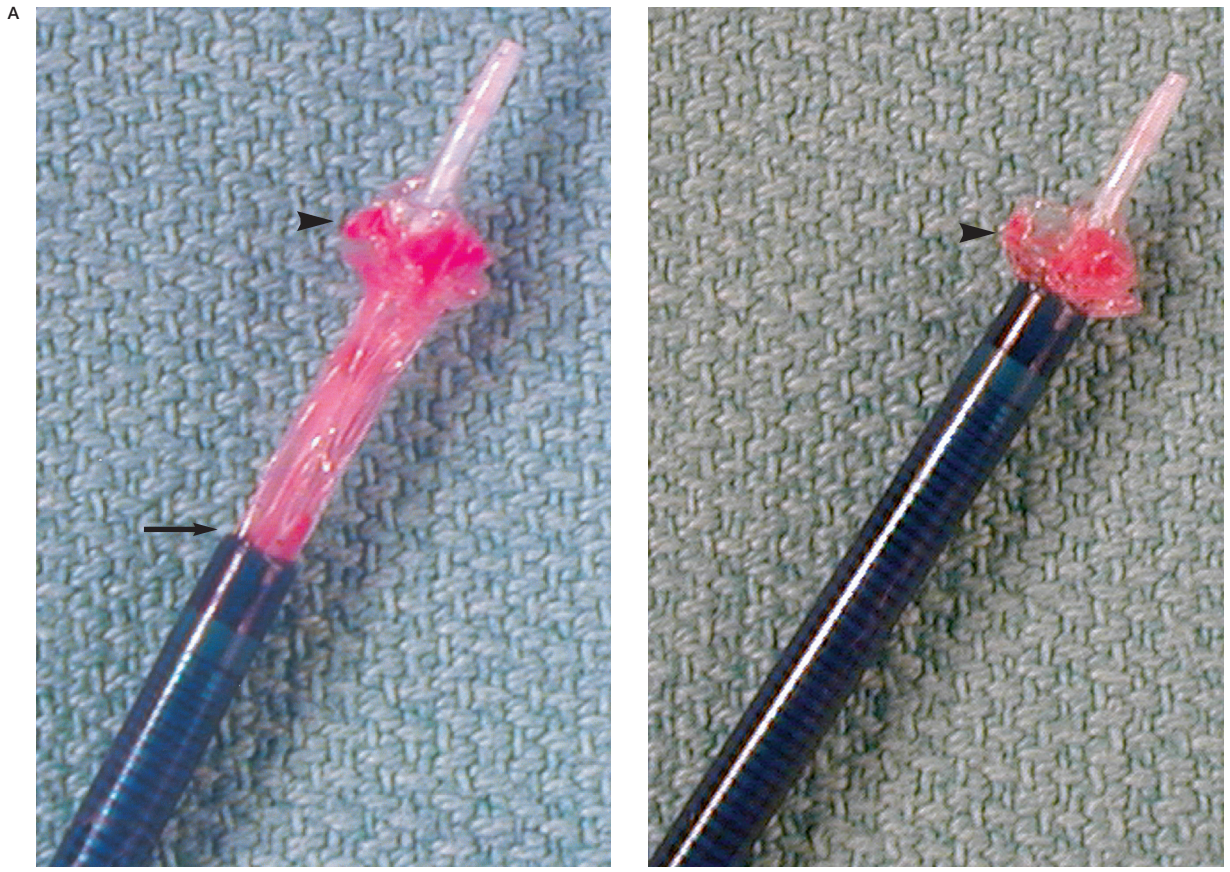

Figure 4 A) The balloon tip (arrowhead) is distended and crinkled as if it had been pulled forcefully into the sheath (arrow) while still inflated. B) This resulted "ball" at the distal end of the balloon (arrowhead) has not allowed its retrieval through the sheath.

treatment, the stagnant column of blood in the occluded internal carotid artery is aspirated before balloon deflation. A second type of device also uses balloon occlusion. But unlike the former, a catheter with two balloons is used proximal to the stenosis. The first balloon is positioned at the common carotid artery while the second balloon is simultaneously inflated in the ipsilateral external carotid artery. As a result, blood flow in the internal carotid is reversed. A particular problem related to the use of occlusion systems is the intolerability of flow arrest in some patients, which may cause loss of consciousness, tremors and fasciculations[9]. The third and most commonly used EPD involves a basket type filter located near the distal end of a wire. Although it is opened distal to the treatment site, it ensures continuous blood flow to the brain while capturing any upstream debris. Several brands of filters are available on the market with little variation in the shape of the basket. All of these are deployed and retrieved in the same way.

The device utilized in the present case comprises a polyurethane filter cone bag fixed on a nitinol loop attached to the distal end of a 200 or 300 cm length and 0.014'' diameter steerable guidewire (figure 5). It is loaded in a monorail 0.052''delivery sheath prior to its placement. Once the filter has been advanced past the target lesion, retracting the delivery sheath while the bare wire is held in place opens the filter. Advancing a monorail 0.056'' retrieval sheath up to the filter loop and pulling on the 0.014" wire allows for closing of the filter and removal of the protective system.

All filter devices currently available exploit the monorail platform. The monorail system was originally developed to facilitate balloon exchange during coronary angioplasty[10]. Essentially, a catheter with a short shaft is threaded by a wire that acts as a rail (monorail). Because

it offers shorter wires, the system has been popularized for use in CAS. Nonetheless, its use may be unadvisable with certain aortic arches in which the common carotid artery stems off at an acute angle. This anatomic disposition creates abrupt, opposing angles that challenge the advancement of the short monorail catheter. The force vector generated during the catheter advancement at the descending arch tends to move it caudally towards the heart instead of cephalically into the carotid artery (figure 3). We postulate that this problem occurs because only a limited segment of the floppy wire is covered by the short distal catheter shaft while the proximal segment of the system, used to advance the catheter, runs uncovered and parallel to the wire. As in our case, it is of particular concern when the support given by the long femoral sheath is lost. Without this support, the bare wire does not allow for sufficient tension to advance the monorail catheter along certain turns.

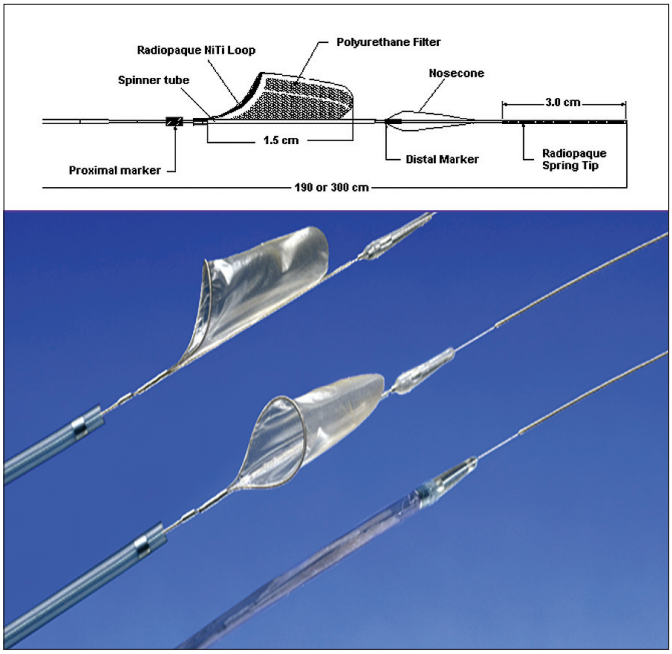

Figure 5 The FilterWire consists of a basket mounted on a shapeable 0.014" microwire. The polyurethane membrane has 110m holes and is attached to a nitinol loop that accommodates 3.5-5.5 mm vessel diameter.

The over-the-wire (OTW) system, however, enables the whole catheter to cover the wire. As a result, the force applied to the proximal end of the catheter is conveyed uniformly throughout its entire length. Being directed along the wire rather than in an angular manner, as in the monorail system, the forward force transmitted through OTW system is in such a way that the advancement of the catheter distal end will follow the wire more easily.

The importance of this added OTW support was well demonstrated in our case with the use of a soft 4 F catheter to rescue the EDP. Fortunately, we had used a 300-cm filter wire that allowed us to exchange the monorail catheter for an OTW catheter. If a 200-cm filter wire had been used, this exchange would not have been possible. The OTW catheter provided adequate tension to advance beyond the turn and successfully complete the procedure.

We can only speculate that a mechanical failure in the balloon system had prevented its total collapse, and an unintentional attempt to pull it while partially inflated caused its deformation precluding its withdrawal. It seems very unlikely that human miscalculation had caused insufficient balloon deflation as the system had been used in many other occasions by the authors without any problems. Though the primary failure in our case was initiated by the balloon system, which forced us to remove the guiding sheath and lose the wire support, the chain of events that followed suggests a serious limitation of the monorail system in the face of an adverse situation. One could argue our bailout attempt to use the monorail retrieval catheter over a bare wire without some sort of support.

However, the minimal guiding catheter inner diameter recommended for the FilterWire use is 0.065", which we deemed too stiff to negotiate the aortic arch over a bare 0.014" wire.

Conclusions

The use of EPDs seems to be necessary for safe CAS. Though the monorail system may offer advantages for a single operator, we caution its use with certain aortic arch anatomies.

In such anatomies, using an OTW system or at least a 300 cm filter wire or devices that support wire extension will remedy some complications, such as the loss of the guiding sheath. As in our case, the added advantage of a 300 cm filter wire enabled us to avoid a poor outcome or an emergency vascular surgery.

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EDITORIAL COMMENT

The authors describe a case of carotid artery stenting using a filter-protection device. After balloon angioplasty, the balloon could not be retrieved via a 6F shuttle sheath necessitating removal of the guiding sheath with subsequent difficulties in retrieving the filter since the retrieval sheath could not be advanced over the aortic arch into the left CCA necessitating exchange of a 4F multipurpose catheter that could be exchanged OTW since the guidewire of the protection device was 300 cm in length.

This is an interesting report on a complication of the combination of materials used and its successful solution. However, the authors only discuss the problem encountered from a single point of view, i.e. concerning the monorail system. Two other potential sources of this complication are not discussed.

Firstly, they used a 6F shuttle sheath which is the smallest possible sheath available for carotid artery stenting for the time being. Unfortunately, we have no information whether the patient encountered any local problems at the puncture site (groin hematoma) that I would fear when removing the sheath with the balloon as demonstrated in figure 4. It is our practice to use a considerably larger shuttle sheath (i.e. 8F). Using this sheath we have never encountered a similar problem with the balloon in more than 500 cases of CAS and I doubt whether the described problem could have occurred using a larger sheath.

Secondly, the use of protection devices in CAS is not without debate. In the presented case, a second appropriate title could therefore be: "A potential pitfall in the use of protection devices for carotid stenting" since it was the protection device (and its retrieval) that caused the problems. As the authors themselves point out, the use of protection devices infers a 0.9% risk of periprocedural complications. Until now, no study has directly proven the benefit of these systems compared to unprotected stenting. The cited SAPPHIRE trial did not include unprotected stenting cases and can therefore not be used as an argument that protection devices are a condition "Sine qua non" for CAS. Yet unpublished data from the SPACE trial demonstrated that the complication rate of unprotected and protected stenting were similar.

Therefore, this case report should not only raise the discussion of whether or not a monorail system should be preferred to an OTW technique, but also whether or not protection devices really add towards patient safety.

Apart from this I would like to add one word of caution. The introductory statement that CAS might be safer and as efficacious as CEA is by no means proven yet. The SAPPHIRE study was able to demonstrate this in a highly selected patient population (high risk patients) and its endpoints (myocardial infarction) are at least a matter of discussion. The SPACE study demonstrated a slight superiority of CEA vs. CAS. The statement that CAS will surpass CEA is therefore at this point in time a little euphemistic and should be stated with more caution.